

VIDAS[®]

Instrument User's Manual



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General Warnings



DANGER!

All biological fluids should be considered as potentially infectious.

Protective gloves must be worn when manipulating blood, products derived from blood or objects contaminated with blood.

Qualified laboratory personnel should use acceptable procedures for biohazardous material.

IMPORTANT!

The configuration that you have purchased is adapted to the legislation and standards of the different countries it will be sent to. For this reason, it may differ from the one presented in this document. However, it will not prevent VIDAS® from operating correctly.

This product is an in vitro diagnostic medical device. It complies with the directives and standards mentioned in the certificate supplied with it.

The user is advised to read and understand all instructions in this manual to be able to derive the best performance from the VIDAS.

bioMérieux® SA recommends that you observe the different warnings inscribed on the instrument itself and indicated in the documentation supplied.

The accuracy of results obtained with this instrument depends, in particular, on the maintenance operations described in this manual. The user should be aware that, if the maintenance operations are not performed, are only partially performed, or are not performed as described in this manual, bioMérieux SA is in no case liable for any false test results obtained.

bioMérieux SA is in no case liable for any changes made to the equipment without authorization from bioMérieux SA.

IMPORTANT!

Electromagnetic Compatibility (EMC):

This is a Class A product.

In a residential area, this product may cause harmful interference in which case the user may be required to take adequate measures at his own expense.

The equipment may also cause interference if not installed in accordance with the instructions given in this manual.

This statement only applies to European countries and instruments



bearing the symbol with regard to the waste electrical and electronic equipment European directive.

You can play an important role in contributing to reuse, recycling and other forms of recovery of waste electrical and electronic equipment. Sorting this type of waste significantly reduces potential negative effects on the environment and human health as a result of the presence of hazardous substances in electrical and electronic equipment.



At the end of the life cycle of this product, do not dispose of the product as unsorted municipal waste, even if it is decontaminated. It is imperative that you contact bioMérieux to assure for its appropriate disposal.

Revisions

The list of revisions below summarizes replacements or additional pages in your **VIDAS** Instrument User's Manual.

Manual	Reason	Page(s)
V.A 03.2005	New VIDAS model	All
V.B 12.2005	New software version	All

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Note: Software screens and figures are given for information purposes only.

1 How to use this manual

Introduction

This manual deals exclusively with the **VIDAS** equipment and consumables.

The software and procedures for use are described in the **VIDAS PC** User's Manual.

The table of contents lists all the chapters of this manual. Each chapter is subdivided into sections corresponding to a procedure or a precise description.

Answers to questions can easily be found by referring to the table of contents, or the index at the back of this manual.

WARNING! *The user is advised to read and understand all instructions in this manual to be able to derive the best performance from the VIDAS.*

Finding topics and procedures

This manual is divided into nine chapters. The first seven chapters are used for the description and procedures. Chapter 8 contains the glossary and chapter 9 the index.

Table of contents

The main table of contents of the manual is located on pages V-1 to V-2. It lists each chapter and the procedures and/or topics contained in the manual.

List of figures

Page VI-1 contains a list of the figures in this manual.

Graphic symbols

The standard symbols used for bioMérieux instruments, and their meanings, can be found in the list on page 1-4.

Page headers and page footers

Apart from the first page of every chapter, each page of this manual includes a page header and a footer.

Each page header includes the chapter title and the title of a procedure or its corresponding description.

These titles are located on the outside of the page so that you can thumb through the pages to quickly locate a chapter or a procedure.

The footers contain the title of the manual, the name of the product and the page number.

Glossary

The glossary is located in chapter 8 at the back of the manual. It gives the definition of the main technical terms used in the manual.

Index

The index is located in chapter 9 at the back of the manual. It is used to locate a particular description or procedure.

Sheet of decontamination labels

One of these labels is applied to the equipment to certify that it has been properly decontaminated:

- before any operation by a service technician,
- before it is returned to the factory, if necessary.

Typographic conventions

1

The following typographic conventions are used throughout this manual.

- Prepare samples...

The bullet point is used to indicate an action to be performed.



This icon is used to indicate specific information concerning the **VIDAS** instrument called "**VIDAS blue**" in the manual.

Unless otherwise specified, the information in the manual applies to the **VIDAS**, whichever model is used.

Warnings

The following warnings are used throughout the manual:

- for safety reasons (**DANGER!**),
- to ensure that **VIDAS** is maintained in good working condition (**CAUTION!**),
- or to allow optimum use of your **VIDAS** (**IMPORTANT!** or **WARNING!**).

Graphic symbols

V.A 09/2003 – māj smn –10/2004

The standard symbols used for the bioMérieux systems and their meanings can be found below:



Direct current



Alternating current



Both direct and alternating current



Three-phase alternating current



Earth (ground) TERMINAL



PROTECTIVE CONDUCTOR TERMINAL



Frame or chassis TERMINAL



Equipotentiality



ON (power supply)



OFF (power supply)



"ON" (only for a component of the system equipment)



"OFF" (only for a component of the system equipment)



Equipment protected throughout by DOUBLE INSULATION or REINFORCED INSULATION (equivalent to Class II of IEC 536)



Risk of electric shock



Caution: see accompanying documents



High temperature



Potential pinch point



Potential biohazard



Consult Instructions for Use



Batch code



Catalogue number



Temperature limitation



Authorised representative of the European Community



Keep dry

How to use this manual

Graphic symbols



Manufacturer



Date of manufacture



In Vitro Diagnostic Medical Device



Serial number



Keep away from magnetic field



Separate collection for waste electrical and electronic equipment

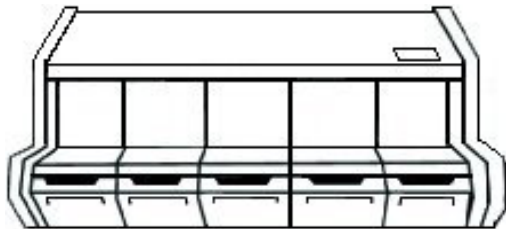
2 Functional description

Introduction

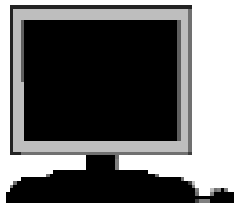
This chapter describes the **VIDAS** instrument:

- its configuration components,
- general features and technical specifications,
- operating principles,
- performance checks / self-tests.

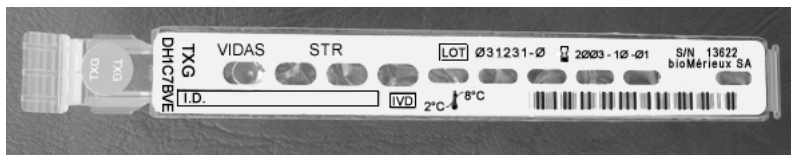
Functional description
Graphic symbols



Analytical module (example)



Computer module (example)



Reagent strip



SPR®

Fig. 2-1: VIDAS configuration

Description / aim

VIDAS is a compact automated multiparametric immunoanalyzer including:

- the **VIDAS** analytical module divided into five independent sections each containing six assays with compatible protocols,
- the **VIDAS PC** software allowing up to two **VIDAS** modules to be operated,
- the reagents presented in kits of 60, 30 or 10 unit tests including :
 - the SPR[®]s and reagent strips,
 - the additional consumables required: standard, control(s), solvent,
 - the factory calibration data provided in the form of a bar code (MLE card),
 - the package insert.

The basic **VIDAS** workflow steps consist of:

- creating predefined sections,
- performing calibrations and controls,
- running assays.

VIDAS offers routine batch or random access (mixed) testing for:

- serology,
- immunochemistry,
- antigen detection,
- industrial microbiology,
- immunohemostasis.

The combination of two original concepts, sectioned architecture and single-dose reagents (SPR/Reagent Strip), offers:

- reliable results,
- ease-of-use,
- rapid analysis results.

VIDAS stands for:

Vitek[®] Immuno Diagnostic Assay System.

The technology used, which is adaptable to a wide range of assays, combines the EIA method with a final fluorescence reading: this technology is known as ELFA (*Enzyme Linked Fluorescent Assay*).

The enzyme used in the **VIDAS** range is alkaline phosphatase.

The substrate is 4-methyl umbelliferyl phosphate (4-MUP) hydrolyzed into 4-methyl umbelliferone.

Umbelliferone fluoresces at 450 nm after excitation at 370 nm.

Configuration components

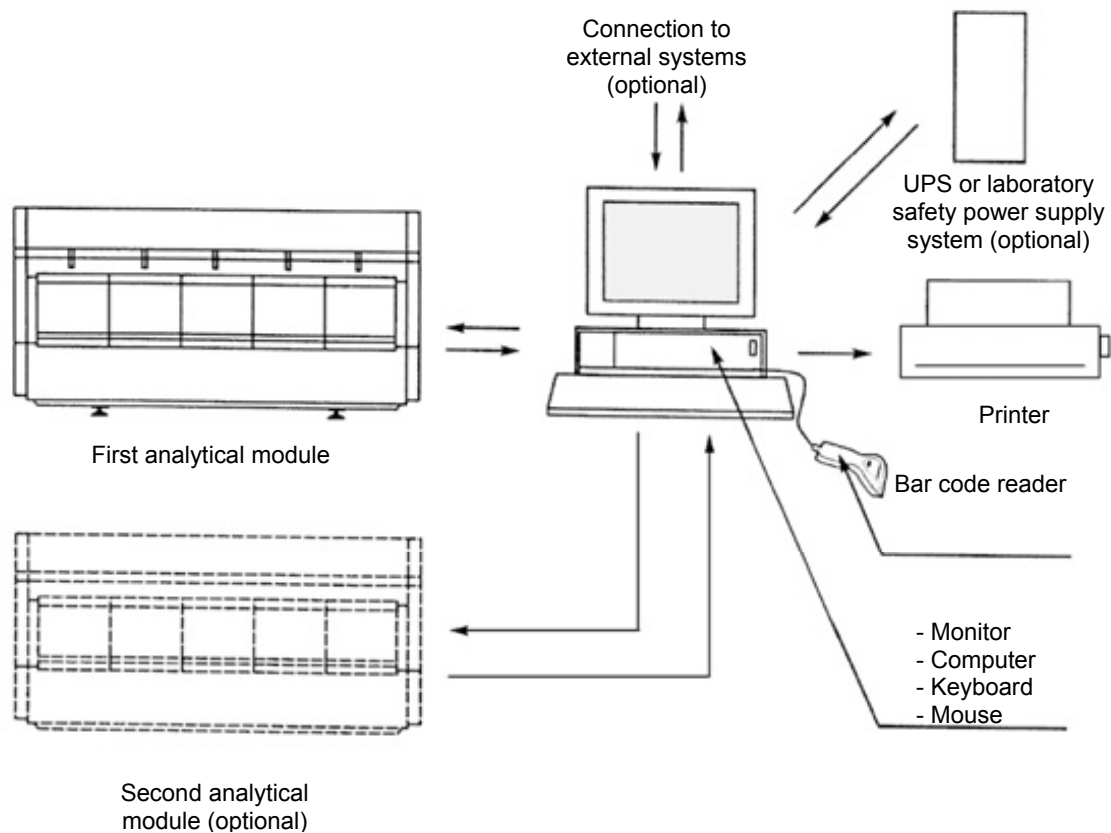


Fig. 2-2: Configuration components (example)

The **VIDAS** can be divided into three categories of components :

- hardware,
- software,
- consumables.

Hardware

VIDAS consists of:

One or 2 analytical modules, each containing 5 sections of 6 positions each (capacity to process over 200 samples per day).

A computer system offering data management, result storage and bidirectional interface with the laboratory information system. This system consists of :

- a computer,
- a screen,
- a bar code reader,
- a printer.

CAUTION! *Never use material other than that specified by bioMérieux®.*

Software

The software is multi-task and provides for:

- entry of patient data and assays,
- storage of calibrations in memory,
- display and validation of results,
- system operation and self-tests,
- management of patient records,
- management of the uni- or bidirectional interface (optional).

IMPORTANT! *Never download into the computer, programs other than those provided by bioMérieux. If these instructions are not complied with, the computer could become infected with computer viruses. Any intervention directly or indirectly resulting from the presence of such a virus cannot be covered by the warranty or the maintenance contract.*

Consumables

Assay kit (60, 30 or 10 tests).

Hardware

Analytical module

General remarks

30 tests can be performed simultaneously: 5 sections (A, B, C, D, E) containing 6 positions each.

Each section is microprocessor-controlled and consists of:

- a transport tray for reagent strips,
- a pipetting system,
- a SPR[®] block for pipetting,
- an incubation system.

Each section operates independently, enabling the analytical module to handle a wide range of tests at one time.

An indicator light on each section shows the current status.

- The indicator light is on when a section is performing an assay.
- The indicator light flashes when the assays are completed.
- The indicator light goes off when the reagent strips and SPR[®]s are unloaded.

The **VIDAS** handles reagents via five six-channel pipetting systems (1 system per section) which carry out all reagent transfers, dilution and washing by means of the SPRs.

The pipetting system handles liquid volumes of between 8.9 µl to 316.5 µl. The system is lowered and raised to give the SPRs access to the wells on the reagent strip.

The six pipetting channels are physically independent but mechanically linked for synchronized operation.

Movement in each section is driven by stepper motors.

The range of movement is determined by parameter-defined protocols.

The assay temperature is 37°C inside the module.

Each module is equipped with two thermal probes per section, which ensure that this constant temperature is maintained.

Microprocessor

In addition to the central processing unit, each **VIDAS** section contains its own microprocessor.

Each microprocessor controls the movements required by each assay, depending on the protocol applying.

Each section is therefore **independent** and **autonomous**.

This unit is responsible for storing and operating assay protocols.

A protocol consists of a series of commands including aspiration of the reagents, washing and optical scanning.

The microprocessor enables the **VIDAS** to perform a fully automated assay.

Reagent strip tray

A plastic cover, located at the lower edge of each section, can be lifted up to reveal the reagent strip tray.

This tray shown in the figure below contains six channels into which reagent strips can be inserted.

Each channel constitutes a section position.

Up to six single reagent strips or three dual reagent strips can be inserted at one time, taking the total module capacity to 30 single tests.



Fig. 2-3: Reagent strip tray

The reagent strip tray is also used for automatic entry of the factory master calibration data (MLE card) using the card holder.

Note: For further information on the MLE card, see the **VIDAS PC User's Manual**.



CAUTION!

The reagent strip trays are movable parts. The risk of finger pinching exists.

Strip preparation tray

(only concerns
VIDAS blue)

A retractable strip preparation tray is located under each reagent strip tray.

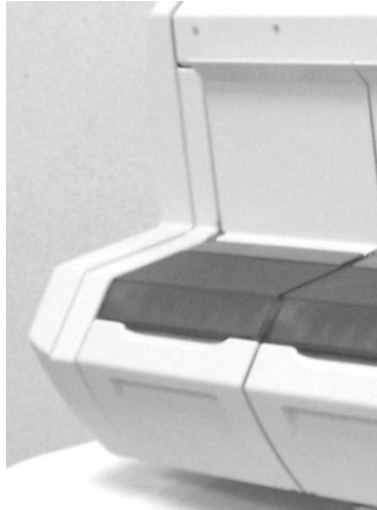


Fig. 2-4: Strip preparation tray closed

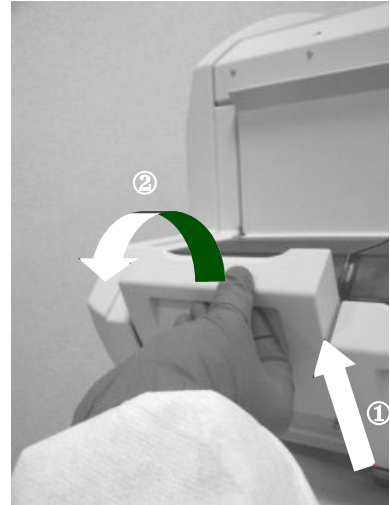


Fig. 2-5: Opening the strip preparation tray



Fig. 2-6: Reagent strips placed on the strip preparation tray

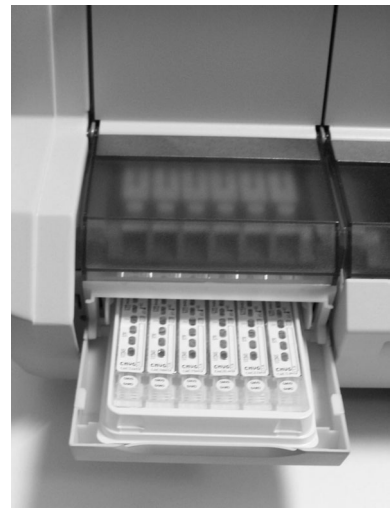


Fig. 2-7: Reagent strips placed on the strip preparation tray with their boat

SPR® block

The upper part of the section includes a tilt-down door which gives access to the SPR block .

The six positions of the SPR block correspond to the six positions of the reagent strip.

During processing, the SPR block and SPRs form a pipetting device that is used throughout the assay.

The reagent is cycled in and out of each SPR by a piston-driven air system.



Fig. 2-8: SPR block

Incubator

Assays using the **VIDAS** require a controlled temperature.

The temperature of each section tray and each SPR[®] block is individually controlled and monitored.

Each tray and SPR block are equipped with a stable high-precision temperature detection system, known as the thermistor.

During manufacture, each thermistor assembly is tested to NIST (National Institute of Standards and Technology) ITS-90 tolerance requirements for temperature measurement.

The thermistors used in the **VIDAS** are accurate to within 0.2°C.

Only thermistor systems that meet this criterion on manufacture are installed in the **VIDAS**.

Note: To display the SPR block and tray temperatures, see the **VIDAS PC User's Manual**.

Bar code readers

Two bar code readers:

- A hand-held bar code reader is included in the **VIDAS** configuration. It may be used to:
 - read the bar codes of certain reagents before they are used. The procedure for using these reagents is described in Chapter 5 of the **VIDAS PC User's Manual**.
 - enter patient data or search for patient data (or a specimen) and read MLE cards.
To install the hand-held bar code reader, see Chapter 4 "Installing the hand-held bar code reader".
- An internal bar code reader enables identification of the reagent strips and reading of the MLE card.

Detection system

The **VIDAS** detection system consists of an optical fluorimetric scanner.

It is mounted on a mechanical device which enables it to be used on all five sections.

The system detects any chemical changes occurring in the optical cuvette at the end of each reagent strip.

Fig. 2-9 shows the position of the optical cuvette on a standard reagent strip.

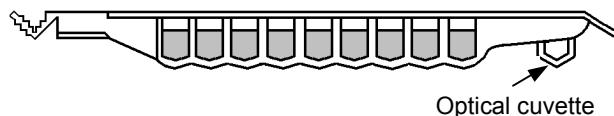


Fig. 2-9: Optical cuvette on a reagent strip

Central processing unit

The central processing unit controls all aspects of the **VIDAS** operations, including data analysis and verification of optical and mechanical systems.

Computer module

The computer is designed to operate the analytical module(s) (up to 2) and to manage assays using the **VIDAS PC** software (see the **VIDAS PC** User's Manual).

It is connected to the module(s) in order to perform automatic analysis of the various assays.

The computer is equipped with peripherals to display, print and store results.

UPS

In the absence of a safety power supply system in the laboratory, the UPS guarantees an uninterrupted power supply.

It protects the analytical module(s) from any electrical disturbances, ensuring that test results are systematically preserved.

Note: For further information on peripherals (computer, etc.), see the enclosed manufacturer's documentation.

Extension potential

- Second analytical module,
- Uni-directional or bidirectional connection (connection to the laboratory information system).

Consumables

Assay kit

Each **VIDAS** assay kit contains the reagents required to run a specific assay.

Kit contents vary for each assay, but generally a kit contains:

- Single or dual reagent strips,
- SPR[®]s (Solid Phase):
 - one for a single reagent strip,
 - two for a dual reagent strip,
- control(s),
- the necessary standard(s),
- a diluent (as required),
- a package insert
- a MLE card.

Single reagent strip

The **VIDAS** single reagent strip contains ten wells. The sample is placed in the first well.

The other eight wells contain the necessary reagents (conjugate, diluent, wash buffer).

The last well is the optical cuvette in which the fluorescence of the substrate is measured.

A small tab ensures that the strip is correctly positioned in its channel guides.

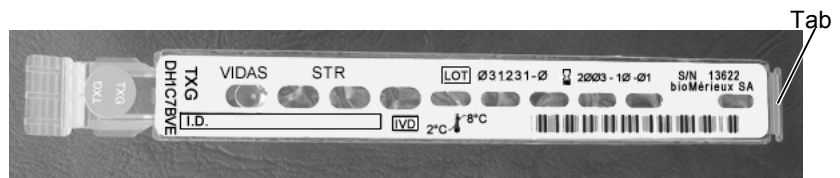


Fig. 2-10: Single reagent strip

Dual reagent strip

Some assays require the use of a dual reagent strip, consisting of two strips side by side.

The sample is divided between the two sample wells on the two reagent strips.

With the strip oriented as shown in the figure below, the upper strip serves as the reference strip and the lower as the sample test strip.

The sample test strip contains a reagent which is not included in the sample reference strip.

A comparison of the measurements from the two strips determines the test result.

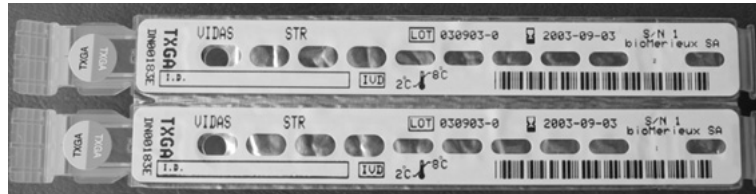


Fig. 2-11: Dual reagent strip

Reagent strip label

Each **VIDAS** reagent strip has a label and a color-coded dot. Both are identified by the same 2-4 character and/or figure code.

The colored dot corresponds to a matching dot on the test's companion SPR®.

The bar code identifies:

- the assay name,
- the manufacturing lot number,
- the sequence number,
- the assay kit expiration date.

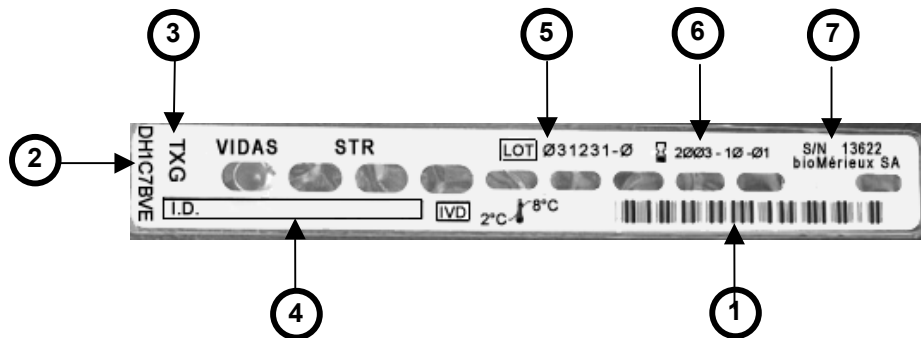


Fig. 2-12: Reagent strip label



Fig. 2-13: Reagent strip dot

<u>Ref.</u>	<u>Description</u>
1: Bar codes	Under normal operating conditions, the internal bar code reader reads the machine readable code.
2: Alphanumeric representation of the bar code	If the system is unable to read this code, the alphanumeric form of the bar code is used to enter the bar code.
3: Assay code	The assay code is based on two or four characters and/or figures which represent the name of the assay to be performed. Examples: – RBG Rubella IgG II – 153 CA 15-3 All references to an assay in the software and on printed reports use the assay code.
4: ID	A blank space is provided to write the sample ID (if necessary) .
5: Lot number	The lot number is used by the VIDAS to code the expiration date of the reagent lot.
6: Expiration date	This corresponds to the expiration date of the reagent lot. When the bar code reader reads this date, the VIDAS compares it to the date stored in its memory to ensure that the lot has not passed its expiration date.
7: Sequence Number	Within a single batch, each reagent tray carries a different number corresponding to the order of manufacture.

SPR®s

Characteristics

The SPR is a plastic (polypropylene or polystyrene) device capable of capturing soluble proteins, viruses and bacteria.

It is sealed with a color-coded dot and perforated in the center. Each SPR® is disposable (see Fig. 2-14).

Functions

The SPR is the solid phase base for the immunological reaction. Its interior walls are coated with antibodies or antigens that capture a target analyte.

The SPR is used to pipette samples and reagents, and eliminates cross-contamination between reagent and instrument. Maintenance is reduced to a minimum since there is no tubing, syringe or sampling needle involved.

Each SPR for a specific assay is identified by a color-coded cap and a letter and/or figure code representing the assay name.

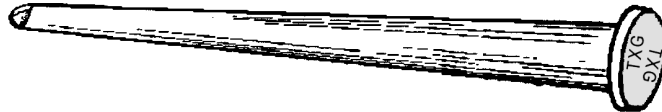


Fig. 2-14: SPR®

The **VIDAS** uses the SPR to perform the following operations:

- sampling,
- incubation,
- mixing,
- washing.

General features and technical specifications

Environmental conditions

Operating temperature:	+ 15° C to + 30° C (59° F to 86° F)
Storage temperature:	+ 10° C to + 40° C (50° F to 104° F)
Relative humidity:	10 to 80%, without condensation
Type of installation:	for indoor use only; light industrial equipment
Installation category (voltage overload category):	II (according to standard IEC 61010.1)
Degree of pollution:	no. 2 (according to standard IEC 61010.1)
Maximum installation altitude:	2 000 m

Physical features

Dimensions

	VIDAS blue		VIDAS	
	Instrument packed	Instrument alone	Instrument packed	Instrument alone
Height	59 cm (23¼")	45 cm (17⅝")	58.2 cm (23")	44.4 cm (max.) (17½")
Width	110 cm (43⅓")	88 cm (34½")	99 cm (39")	84.7cm (33⅓")
Depth	66 cm (26")	55 cm (21⅝")	67.5 cm (26⅝")	52.4 cm (20⅝")

Space requirements

	VIDAS blue	VIDAS
Height	65 cm (25⅝")	65 cm (25⅝")
Width	150 cm (59")	150 cm (59")
Depth	90 cm (35½")	90 cm (35½")

The instrument must be placed on a flat surface with a maximum horizontality defect of 5°.

Weight

	VIDAS blue		VIDAS	
	Instrument packed	Instrument alone	Instrument packed	Instrument alone
Mass	75 kg (165½ lbs)	65 kg (143⅓ lbs)	71 kg (156½ lbs)	61 kg (134½ lbs)

Sound level Sound level: ≤ 59 dBA

Electrical specifications

Class I equipment

2

	VIDAS blue	VIDAS
Voltage	100 – 240 VAC 3 - 1.2 A	100 - 120 VAC 200 - 240 VAC <i>Nota : The voltage (100 - 120 VAC or 200 - 240 VAC) is selected using the power supply unit at the rear of the module.</i>
Consumption	280 VA	200 VA
Frequency	50-60 Hz	50 – 60 Hz
Safety fuse	External : 4.0 AT	External (power input module) 3.0 AT at 100 - 120 VAC 1.6 AT at 200 - 240 VAC
Approximate emission of heat	921 Btu/hr 270 W	512 Btu / hr (rated) 150 W
Power switch	Location : Back of the module Type : bipolar (live + neutral) Maximum leakage current: < 1 mA	
Internal code bar reader	The instrument includes an internal bar code reader with a 660 nm LED whose radiation is Class 1 according to IEC 60825-1. This class does not present a risk.	

Functional description

General features and technical specifications

Technical specifications

Processing capacity

- 30 test positions:
5 sections each containing 6 positions.
- Up to 50 tests/hour depending on the type of test used (see test duration indicated on each **VIDAS** assay package insert).

Motors

- Automatic control by means of stepper motors.

Pumping

- 5 pumps: one per section.
- Mixing, dilution and transfer of reagents.

Temperature control

Absolute precision

SPR [®] blocks:	$37 \pm 1^{\circ}\text{C}$
Section tray:	37°C (-2°C , $+1^{\circ}\text{C}$)

Relative precision

SPR blocks:	$\pm 0.7^{\circ}\text{C}$ (against the average of all the SPR blocks)
Section tray:	$\pm 1^{\circ}\text{C}$ (against the average of all the section trays)

Process

Thermal resistance

Automatic control

By thermal probes

Characteristics of optical components

Detector	Fluorimetric photodiode
Detection range	40 to 40000 nmol of 4MU (4-Methyl Umbelliferone)

Automatic self-testing

Automatic self-testing of the optical system every 12 hours against a benchmark standard (known as the "Solid Standard").

Automatic recalibration if the deviation from the Solid Standard is ≥ 0.6 %.

Assay kit

SPR[®]

Length:	76 mm	(3 inches)
Composition:	plastic polymer	
Work volume:	5 - 350 μ l	

Reagent strip

External dimensions

	VIDAS assay
Length	157 mm (6.2 inches)
Width	18 mm (0.7 inches)
Depth	15 mm (0.6 inches)

Well capacity

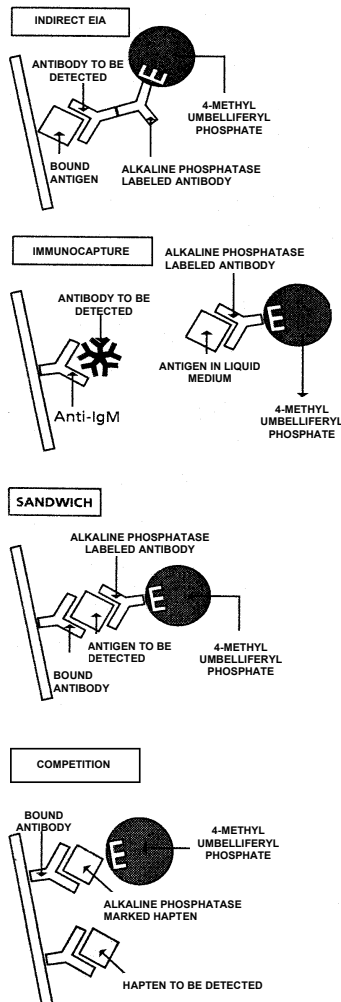
Sample well:	960 μ l
Reagent well (8):	960 μ l
Substrate well:	530 μ l

The strip is covered by foil which seals the wells and prevents any evaporation that might compromise the reagents.

The substrate well is made of a plastic which has the appropriate optical qualities.

Operating principles

Immunoassay methods



Detection of antibody

The antigen is coated on the interior walls of the SPR®.

If the sample contains the antibody to be detected, the 4-methyl umbelliferyl phosphate is hydrolyzed to umbelliferone.

Detection of immunoglobulins M

The IgM to be detected is captured by the anti-IgM coated on the interior walls of the SPR.

The presence of the IgM is detected by the Ag stabilized in liquid medium.

Detection of antigens (bacterial, viral, protein, ...)

The interior wall of the SPR is coated with antibody.

In the above three methods, the fluorescence levels measured are directly proportional to the quantity of antibody or antigen present in the sample.

Detection of haptens (hormones, ...)

The interior wall of the SPR is coated with a limited quantity of antibody.

The hapten to be detected competes with the labeled hapten.

The fluorescence level measured is inversely proportional to the quantity of haptens present in the sample.

Protocol concept

Definition

A protocol defines a specific sequence of operations required to perform an assay. It therefore covers :

- sample volume,
- incubation time in the SPR[®],
- frequency of cycling of reagents in and out of the SPR,
- movements of the SPR and the reagent strip,
- final reading.

Assays using the same protocol can be carried out in the same section.

The **VIDAS** will automatically group compatible assays.

Method

The sample (serum or pre-treated) must be placed in the sample well on the reagent strip as indicated in the appropriate assay package insert.

The sample volume required varies according to the test and is given in the assay package insert.

The reagent strip slides horizontally to position the required well under the SPR.

The SPR moves up and down so it can perforate the foil seal and pipette the required reagents.

Dynamic reactions:

At each stage, the reagent is cycled in and out of the SPR several times. This increases reaction kinetics and reduces incubation times.

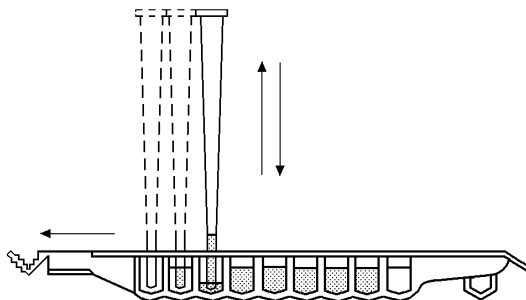


Fig. 2-15: Dynamic reactions

Different stages of the protocol

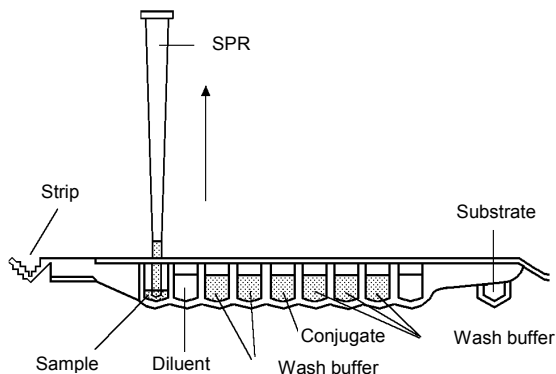


Fig. 2-16: Example of a protocol

Reagent check

Before starting the assay, the system checks the reagent; it scans the bar code, reads substrate fluorescence and checks the expiration date of the strips.

Any anomaly is reported on the screen.

Bar code scanning error (ERRCB)

This error report will be generated if the reagent strip does not correspond to the assay requested, if the corresponding protocol is not activated, if the strip is not properly inserted or if the scanner has difficulty reading the bar code. If the scanner has difficulty reading the bar code, it can be entered manually.

This error report will also be generated if you have inserted more strips than expected.

Whatever the cause, refer to the **VIDAS PC** User's Manual.

Substrate fluorescence error (ERRSUB)

The software contains standard fluorescence levels designed to guarantee reagent quality.

If levels measured do not fall within the standard range, a warning appears on the screen and the fluorescent value of the substrate can be displayed in the Error Reporting Menu.

Kit not calibrated or expired calibration (ERRCAL).

Expired lot (ERRLOT)

- Rerun the assay with a valid lot.

Immunological reaction

The SPR[®], coated with antigen or antibody, is brought into contact with the sample, the conjugated antibody and the substrate.

SPR washing operations are also programmed.

Determining background

At this stage, the **VIDAS** makes a fluorescent reading of the substrate. This fluorescence value will appear on the result sheet under the heading BKG (background).

Chemical reaction

The 4-methyl umbelliferyl phosphate is hydrolyzed to 4-methyl umbelliferone by the alkaline phosphatase in the SPR.

Fluorescent reading

The intensity of the final reaction is measured in the optical cuvette on the reagent strip.

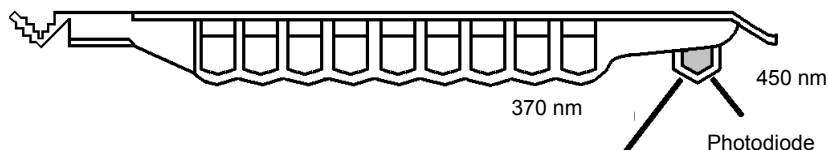


Fig. 2-17: Fluorescent reading

Optical system

The **VIDAS** optical system measures the concentration of reagent developed during the assay, using a single channel fluorometer.

This optical system uses dual beam excitation to compensate for variations in the lamp output.

The optical system can be moved through the module to read the required test. The reagent then produces a fluorescent signal proportional to its concentration.

Performance checks / self-tests

Optical system

Calibration principle

The module's optical system is controlled and calibrated by a bioMérieux® technician during maintenance operations. To do so, the bioMérieux technician uses a standardized solution of 4-MU in a buffer (see Manual Calibration).

Once the module is correctly calibrated, it measures the fluorescence of the solid standard and then stores this value in the **VIDAS** system's permanent memory.

This value then becomes the reference point for all future calibration checks.

Optical system self-tests

The **VIDAS** carries out periodic readings in air and on the solid standard and sends an error message if these readings fall out of expected bounds.

Manual calibration

The instrument is calibrated against a standard solution contained in **VIDAS** strips of the same design as reagent strips.

Specific fluorescence values are assigned to these calibration strips.

This corresponds approximately to a reading of 3200 RFU with a solution of 4-methyl umbelliferone (4-MU) of 8000 nmol in a buffer.

Manual calibration of the module is performed by a bioMérieux technician during maintenance operations.

Autocalibration

The **VIDAS** optical system has proven to be highly reliable and stable over many years of use.

As a further step in checking system performance, the **VIDAS** also uses a reference to compensate for any drift in the optical system.

The **VIDAS** module therefore incorporates a specific material (fluorescent europium) embedded in an optically clear polymer, to serve as an optical reference (also known as the solid standard).

This reference enables the **VIDAS** to check the entire optical system and correct the variations likely to cause the level of fluorescence to drift.

The long-life reference material is placed in a well inside the module, between sections A and B. The optical system periodically measures the reference and the results are monitored by the **VIDAS** to ensure that optical drift is minimal.

Every 12 hours, the **VIDAS** carries out a calibration check, consisting of three readings of the solid standard. It averages out the results and compares the average against the value in memory.

The **VIDAS** automatically recalibrates if it finds a difference greater than 0.6 % (a variation of 19 RFU for a value of 3200 RFU) from the value in memory.

The recalibration is carried out automatically by three new readings. The new average value calculated must this time be less than 0.4% (13 RFU for a value of 3200 RFU) of the value in memory.

The series of readings continues until this level of 0.4% is reached by successive recalibrations.

If the value of the optical calibration changes by more than 3% (96 RFU for a value of 3200 RFU), an error message which does not block the system (ERROR 160 see chapter 12 "Troubleshooting" in the **VIDAS PC** User's Manual) will inform you. Unless this error occurs while your instrument is warming up (see chapter 3 "Getting started" in the **VIDAS PC** User's Manual), call your bioMérieux® Technical Assistance so that the instrument can be checked before a problem arises.

If the system is reaching the end of its recalibration capacity, ERROR 161 is generated (see chapter 12 "Troubleshooting" in the **VIDAS PC** User's Manual). Call your bioMérieux Technical Assistance Dept. immediately.

Pipette mechanisms

Calibration and self-tests

On-site calibration of the pipette mechanisms is not necessary.

Controls of pipette mechanism precision during manufacturing include physical inspection, pressure and volume checks on each module and a liquid transfer check carried out on the fully assembled equipment before shipment.

When an assay is performed, the **VIDAS** checks the movement of the pipette mechanisms. If there is any variation from the expected movement, the assay is automatically halted and the computer sends an error message.

Field checks of the pipettor accuracy may be accomplished by using bioMérieux® controls.

VIDAS temperature

Self-tests

The SPR®/strip environment is maintained at a controlled temperature. Each SPR block includes a heating element and a temperature sensor. The same principle is applied to the reagent strip section trays.

The temperature of each section is individually regulated. An error message is generated if the temperature moves out of the required range.

The sensor sends the measured value to the section microprocessor which responds by regulating the heating element accordingly.

SPRs are kept at a constant temperature of $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ which must not vary by $\pm 0.7^{\circ}\text{C}$ from the average for the five compartments.

On the same principle, the reagent strip section trays are maintained at 37°C (-2°C , $+ 1^{\circ}\text{C}$) with a maximum variation of $\pm 1^{\circ}\text{C}$ from the average for the five sections.

If a temperature error occurs, the **VIDAS** halts all assays in progress. No further assays can be launched in this section until the temperature returns to its normal operating range.

3 Getting started

Introduction

This chapter gives recommendations for installation and use of the **VIDAS** instrument.

CAUTION!

You are advised to read this chapter in full and follow the different instructions in order to use the VIDAS correctly.

Recommendations for installation and use

In order to facilitate assembly, it is recommended that the components are unpacked and the instructions below are carefully read before starting.

CAUTION!

The VIDAS weighs 65 kg (143 ½ lbs). Two people should lift it out of its box and place it on the benchtop.

The instrument must be placed on a flat surface with a maximum horizontality defect of 5°.



The VIDAS blue should be lifted or moved using the gripping area located on its base.

Before unpacking the instruments, it is advisable to have previously planned where they will be placed.

Avoid exposing the equipment to direct sunlight, excessive heat, humidity or dust.

Only power cords and accessories supplied by bioMérieux® SA should be used to connect the instruments.

Nothing should be placed on top of the connection cables, whether temporarily, permanently or intermittently. Cables should not be laid across passage-ways.

Computer cables must not intersect or be placed too close to one another.

Cables should not be allowed to form loops or knots, or be rolled up near or on other electrical equipment.

All connections should be performed with the power OFF.

Before connecting the system to the power supply, check that all switches are in the OFF position.

The electrical supply to which the system is connected must conform to current standards:

- diameter of cables,***
- grounding,***
- protection through circuit breaker and/or use of fuse,***
- connector calibration and type...etc.***

CAUTION! *The electrical power supply must be:*

- *direct,*
- *individual,*
- *calibrated,*
- *protected,*
- *compatible with the technical specifications of the product or configuration.*

No other electrical equipment likely to interfere with the proper functioning of the system should be connected on the same circuit.

Extension sockets and serially connected adapters should not be used.

If the power supply is not sufficient to guarantee proper functioning of the product, an independent protective device, adapted to the product's technical characteristics should be used.

Do not use power sockets controlled by wall-mounted switches or timers. Accidental power cuts may destroy information in both the analytical module and the computer memories.

No electrical equipment likely to cause interference (equipment not bearing the CE mark...) should be operated in the immediate vicinity of the system.

The safety connection (ground) should not be interrupted by an extension cord without a protection (ground) conductor.

Before connecting or disconnecting the connecting cables, check that the power supply cords of the CPU and all the units connected to it are themselves disconnected.

When adding units to the system or removing them, disconnect the power cables to these units before connecting or disconnecting the connecting cables.

Never connect the VIDAS to the same power supply as devices which generate high current surges (centrifuges) or which, due to frequent start-ups, generate interferences if they are ill-protected (freezers, water baths...).

Unpacking the VIDAS

Before opening the boxes, make sure that no damage has been caused during transport.

If damage has occurred, make a claim to the transport company and notify bioMérieux®.

When opening the boxes, make sure that all the items in the packing list have been delivered.

If possible, keep packaging materials in case the **VIDAS** instrument has to be moved in the future.

CAUTION!

Any damage directly or indirectly resulting from the transport of the instrument without adequate containers will not be covered by the warranty or maintenance contract.

The VIDAS weighs 65 kg (143 ½ lbs). Two people should lift it out of its box and place it on the benchtop.

The instrument must be placed on a flat surface with a maximum horizontality defect of 5°.

The VIDAS blue should be lifted or moved using the gripping area located on its base.

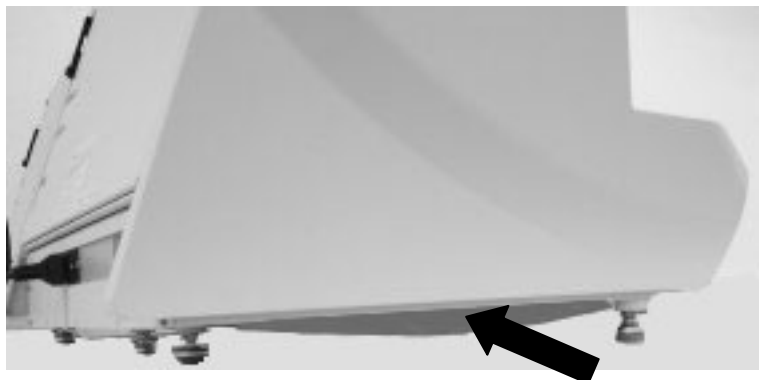


Fig. 3-1: Gripping area (only concerns **VIDAS blue**)

Assembly and installation

This manual contains information and warnings which have to be respected by the purchaser or the lessee to ensure safe operation and to maintain the instrument in good condition.

CAUTION! *The system must be installed and brought into service by or under the guidance of bioMérieux® Technical Assistance.*

After installation, users are given training to help them make the most of their VIDAS system in the shortest possible time.

bioMérieux Technical Assistance must be contacted before moving the equipment, failing which, any such action is taken entirely under the user's responsibility.

Never download into the computer, programs other than those provided by bioMérieux. If these instructions are not complied with, the computer could become infected with computer viruses. Any intervention directly or indirectly resulting from the presence of such a virus cannot be covered by the warranty or the maintenance contract.

The computer media (floppy disks or CD ROMs) containing the VIDAS software programs or the user's backups used for installation or reinstallation must be stored in an appropriate location.

The different elements composing your VIDAS: hardware, software programs, software configuration (especially date and time format, language, type of keyboard, ...) are part of a configuration validated by bioMérieux SA. Any modification or addition resulting in a different configuration to the one validated may cause incorrect operation.



DANGER !

Any break in the grounding protective conductor inside or outside the equipment or disconnection of the protective ground terminal may render the equipment dangerous. Deliberate interruption of such conductors is forbidden.

Opening the covers or removing components, except those maneuverable by hand, may give access to parts that can be dangerous if touched.

Disconnect the instruments prior to any adjustment, replacement, servicing or repair requiring them to be opened.

After opening, if it is imperative to switch the instrument on, any adjustment, servicing or repair should be performed by a qualified technician, well aware of the possible risks.

During a storm, never connect cables to the keyboards/screens, printer or telephones, or lightning conductors to the transmission lines.

Choosing a location

CAUTION!

Avoid exposing the equipment to direct sunlight, excessive heat, humidity or dust.

To ensure that the temperature control maintains the temperature at 37°C, the system must be set up in a room with an ambient temperature of between 15°C and 30°C.

Leave sufficient clearance around the analytical module for the circulation of air, essential to proper temperature control, and for easy access to the power switch.

Do not install the UPS near the right-hand side of your analytical module.

4 Starting the *VIDAS*

Introduction

This chapter describes:

- the procedure for switching on the **VIDAS** instrument,
- the procedure for installing the hand-held bar code reader.

Switching on

After you have assembled and installed the various **VIDAS** components, ensuring that the safety instructions set out in Chapter 3 "Getting started", have been correctly followed, proceed as follows:

- Step 1
- Switch on the UPS, if required.
- Step 2
- Switch on the analytical module and **leave it to warm up for 45 minutes**.

CAUTION! *The power switch is located on the back of the analytical module. It must be easy to reach at all times.*

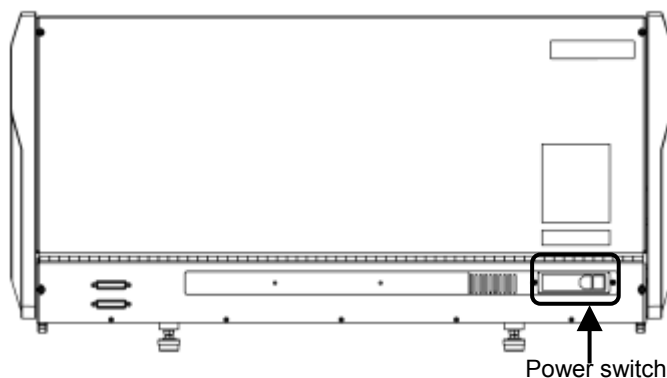


Fig. 4-1: Power switch

- Step 3
- Switch on the printer and screen.
- Step 4
- Switch on the computer.

Refer to the section entitled "Starting **VIDAS PC**" in Chapter 3 of the **VIDAS PC** User's Manual.

- Step 5
- Turn the power switch on the analytical module to the "OFF" position.
- Step 6
- Wait for 1 minute and turn the power switch to the "ON" position.

The **VIDAS** proceeds to self-test its mechanical and optical systems.

All these operations take about ten minutes, during which time the **VIDAS** cannot be used to run assays.

The **VIDAS** can only be used once the self-test phase is completed. The user is alerted by the appearance of the message "AVAIL" on the section status.

Installing the hand-held bar code reader

Preliminary instructions

IMPORTANT! *You are advised to read this procedure in full and follow the different instructions in order to use the bar code reader correctly.*

Each VIDAS configuration in your laboratory should be equipped with a hand-held bar code reader. Repeat this procedure for each computer dedicated to your VIDAS configuration.

Perform this procedure BEFORE using new VIDAS reagent kits.

Note: This procedure does not involve the analytical module. It only applies to the VIDAS PC software host computer.

Starting the VIDAS

Installing the hand-held bar code reader

Preparing the computer

The computer should be switched on.

Checking the keyboard language

Check the **VIDAS PC** computer keyboard language before configuring the bar code reader. To do this,

On the Windows® desktop:

1. click on the **start** button in the bottom left-hand corner of the screen (or press one of the "Windows" keys situated either side of the space bar).
2. Select "Settings", "Control Panel" and "Regional and Language Options".

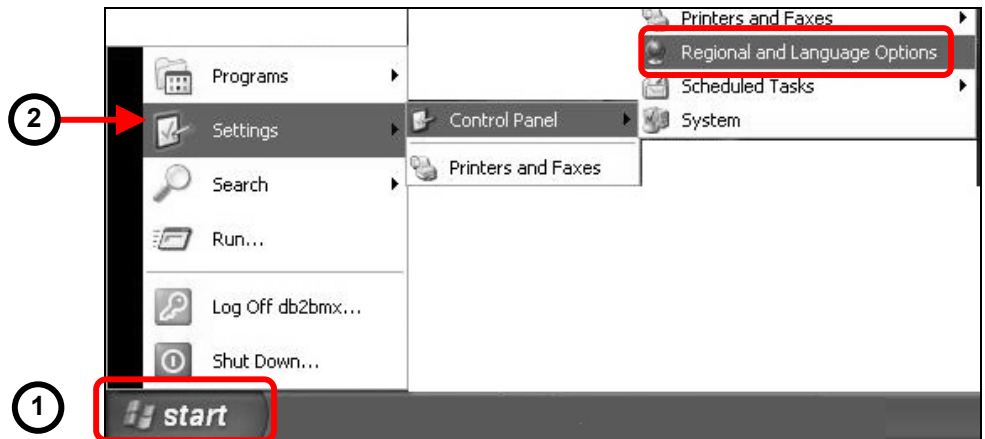


Fig. 4-2 : Configuration options

The options screen is displayed.

3. Select the "Languages" tab.

4. Click "Details..."

The "Text Services and Input Languages" window is displayed.

5. Select the "Settings" tab .

6. The default language is indicated:

- Note down this information which will be required for configuration of the reader.

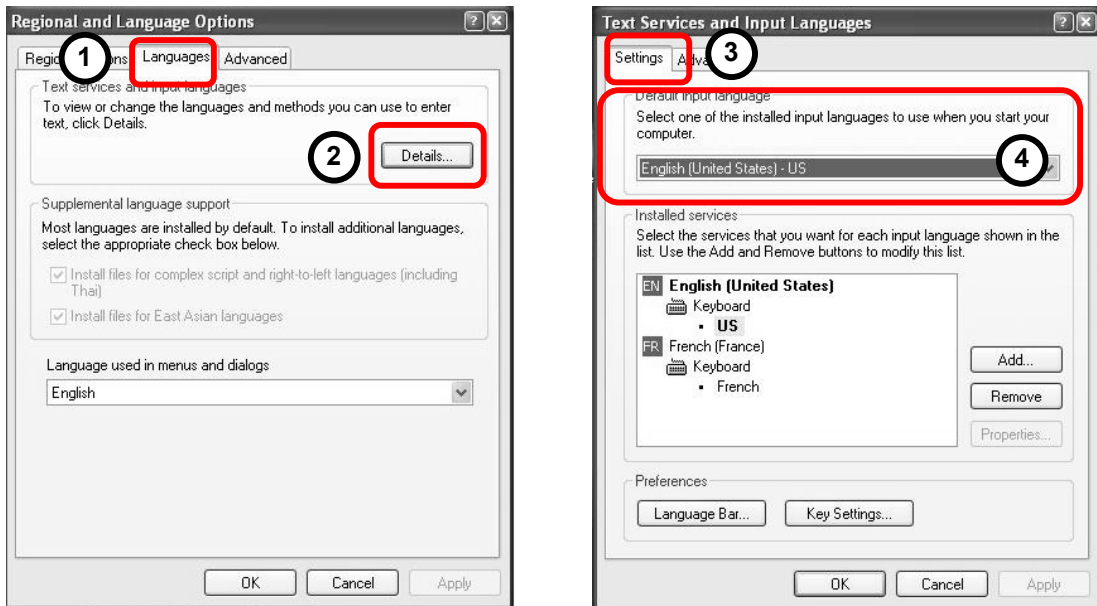


Fig. 4-3 : Configuration details

- Click  to close the different option windows and return to the Windows® desktop.

Starting the VIDAS

Installing the hand-held bar code reader

Switching off the computer

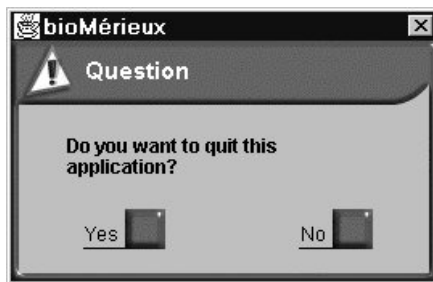
The **VIDAS PC** host computer should be switched off. To do this,

- Make sure that:
 - no assays are running,
 - no reagents (strips and SPR[®]s) remain in the strip sections and SPR[®] blocks,
 - printing is not in progress.

To quit the **VIDAS PC** software:

- click on the stop icon  in the top right-hand corner of your work window.

The following dialog box displays.



- Click on "Yes".

The Windows[®] desktop displays.

To quit the **BCI RS232** or **BCI-NET** software (if necessary),

- click on the stop icon  in the top right-hand corner of the BCI window.
- Follow the instructions in the dialog box corresponding to the BCI software installed on your computer.

The Windows[®] desktop displays.

To shut down the computer:

- Click on the  button in the bottom left-hand corner of the screen or press one of the "Windows" keys situated either side of the space bar,
- Select "Shut Down..."

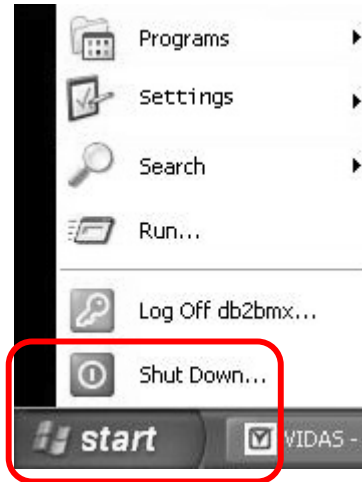


Fig. 4-4 : Shutting down Windows®

The following window appears.

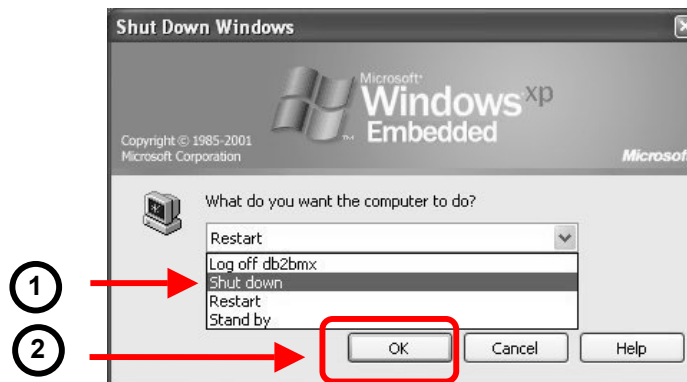


Fig. 4-5 : Shutting down the computer

1. Select "Shut down".
2. Click "OK".

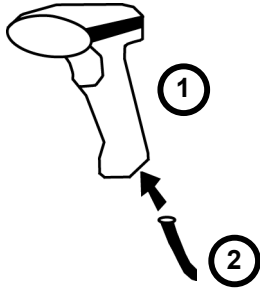
The computer will stop and shut down.

For further information, refer to the **VIDAS PC** User's Manual.

Starting the VIDAS

Installing the hand-held bar code reader

Preparing the reader



The reader is supplied in a kit containing:

- 1 bar code reader (1),
- 1 cord (2),
- 1 configuration sheet.
- Connect (2) to (1).

The bar code reader can now be connected to the computer.

Note: The kit must include the above mentioned components. If any are missing, call bioMérieux® Technical Assistance or your local bioMérieux representative.

Connecting the bar code reader

Note: The bar code reader preparation procedure must have been previously performed.

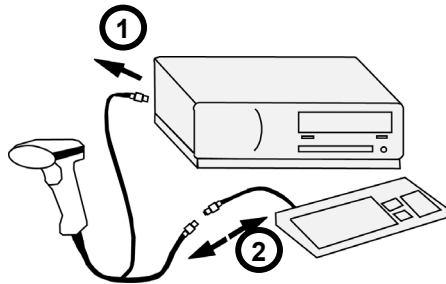
There are two possibilities:

- The system is already equipped with a reader: perform all the steps described below.
- The system is not equipped with a reader: proceed directly to step 2.

Step 1

Disconnect the reader:

- If the cord connecting the reader to the computer is Y-shaped:
- Disconnect the Y-shaped cord from the keyboard port on the computer (1) and from the keyboard cord (2) (see diagram below).



- Reconnect the keyboard cord to the keyboard port (1)).
- Proceed to step 2.
- If the cord is directly connected to the computer:
- Disconnect the reader cord from the connection port (USB port)
- Proceed to step 2.

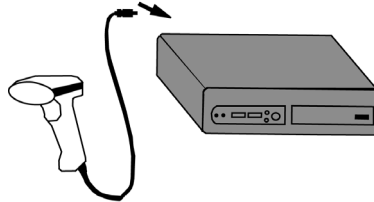
Step 2

Connecting the bar code reader:

The bar code reader cord must always be connected to a USB port. This port may be located at the back and/or at the front of the computer depending on the **VIDAS** configuration.

It is flat and is identified by the symbol .

- Connect the reader cord to a USB port (the figure below shows the connection at the back of the computer).



***Note:** For systems which were already equipped with a reader, use the USB port to which the old reader was connected.*

Step 3

- Switch the computer back on.

The reader initializes and emits 2 beeps.

- Wait for the Windows® login screen to display.
- Enter your user name and password.

***Note:** If the VIDAS is switched off, follow the instructions in section "Switching on, page 4-2.*

If the **VIDAS** system was already equipped with a reader, the old reader's configurations will be replaced by the **default** configuration of the new bar code reader.

Configuring the bar code reader

IMPORTANT! *The reader you have received has already been configured by bioMérieux and takes into account most of the existing types of bar codes. Should the reader lose its configuration, refer to the following procedure.*

Before configuring the bar code reader, check that:

- the reader has been assembled and connected,
- the computer is switched on and a session is open (the Windows® desktop is displayed).
- the configuration sheet included in the bar code reader kit is available,
- the information concerning the keyboard language (checked during the "Checking the keyboard language" step) is available.

IMPORTANT! *Before configuring the bar code reader, check that the upper case key (<Maj> or <Caps lock>) is disabled.*

- Follow the instructions on the configuration sheet.

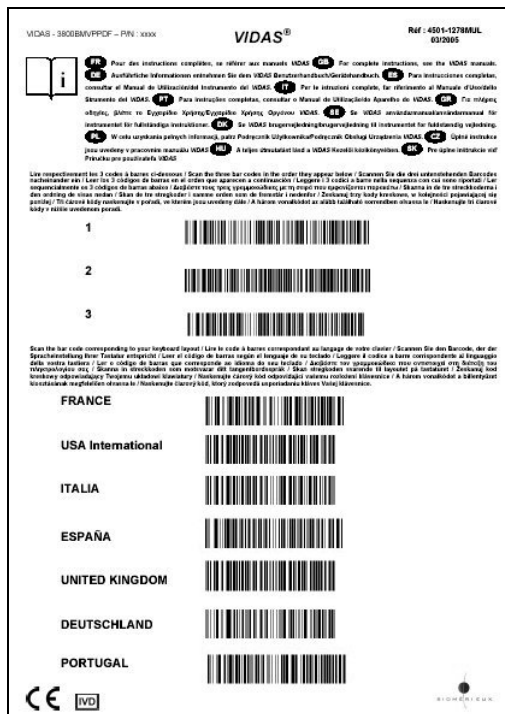


Fig. 4-6 : Example of a reader configuration sheet

At the end of configuration, the reader is ready for use.

Recommendation for use of the bar code reader

To read a bar code:

- Hold the reader about 5 cm from the bar code.
- Check that the reader is perpendicular to the bar code (maximum 5° tilt).
- Depress the trigger.

A red beam of light will appear on the bar code.

- Hold the trigger and slowly scan the bar code from top to bottom or bottom to top until the code has been read completely.

A beep and a green LED indicate that reading has been performed correctly.

Nota : If pdf bar codes are read, refer to the **VIDAS PC User's Manual**, Chapter "Updating a **VIDAS** assay".

When reading is complete:

- Release the trigger.

If reading does not occur immediately:

- Slowly move the reader away from and/or towards the bar code until the optimal position for reading has been reached.
- If the problem persists, refer to Chapter 7 "Troubleshooting".

5 Using *VIDAS*

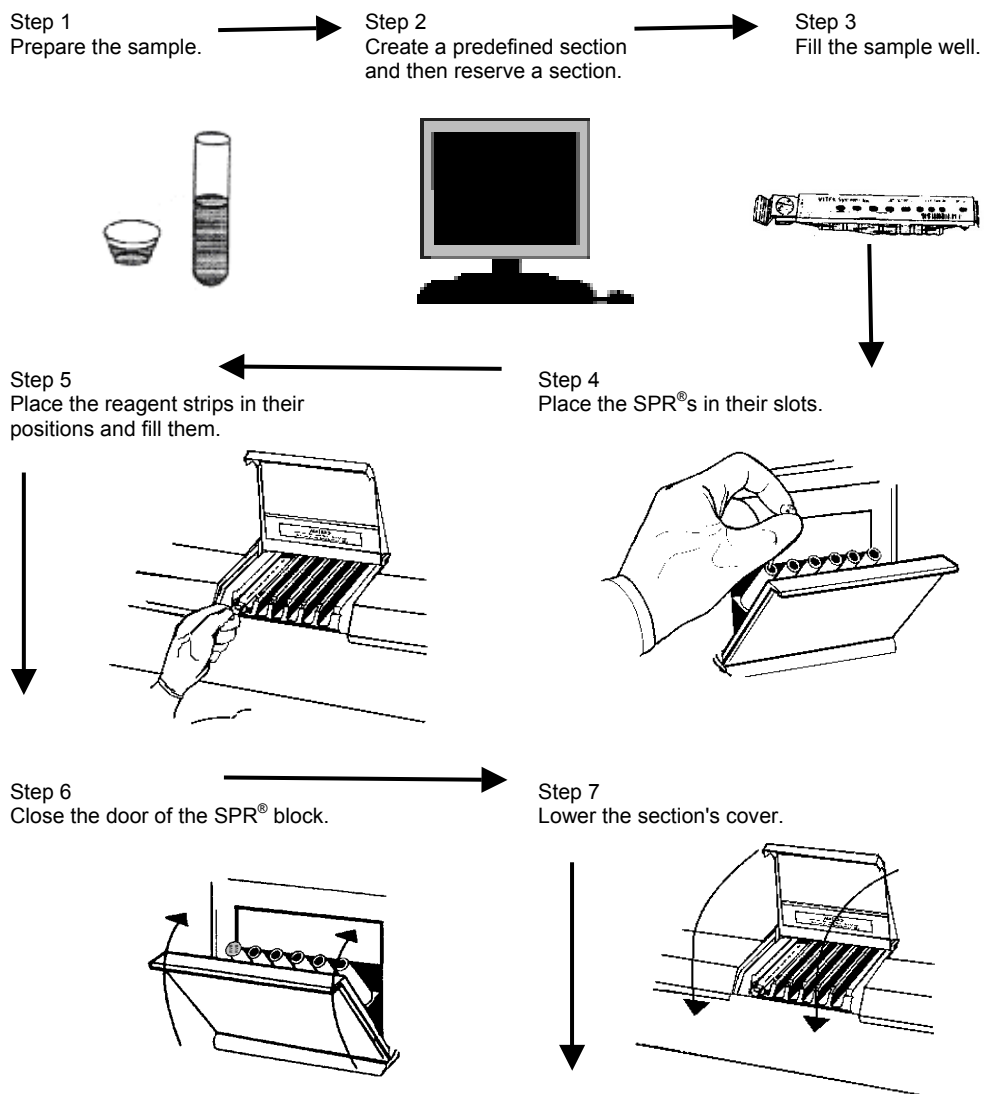
Introduction

This chapter contains the procedure to be followed to carry out routine operations on the **VIDAS**.

Before applying these procedures, you will have already:

- switched on **VIDAS**.
- defined the system configuration options explained in the **VIDAS[®] PC** User's Manual.

Basic VIDAS work flow



(Basic VIDAS work flow continued on next page)

Fig. 5-1: Basic VIDAS work flow

Step 8
Run assays.



Step 9
Results are printed (depending on the software configuration).



Step 10
When assays are completed, remove the reagent strips and SPRs.

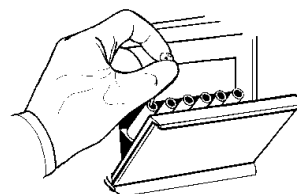


Fig. 5-2: Basic VIDAS work flow (cont'd)

Note: For details of routine use of your VIDAS, refer to the VIDAS PC User's Manual.

The following procedure outlines the common work flow steps that are used for VIDAS immunoassay tests.

Sample preparation steps, which may vary from one assay to another, are described in the package insert of each assay.

The VIDAS blue strip preparation tray can be used to bring the reagents to room temperature (see Fig. 2-6 and 2-7, on page 2-8).



CAUTION! Never dispense samples into the reagent strips when they are on the strip preparation tray.

The strip preparation tray should only be used for reagent strips. Do not place samples on it.

IMPORTANT! Always observe good laboratory practices and universal safety precautions when handling VIDAS assays.

If the test is being used for the first time, its data must be updated in the VIDAS PC software. Follow the instructions in Chapter 5 "Updating a VIDAS assay" of the VIDAS PC User's Manual.

Step 1

- Prepare samples as described in the appropriate assay package insert.

Step 2

- Create a predefined section, reserve a section and generate a loading report (see VIDAS PC User's Manual).

Step 3	To fill a reagent strip, • Place the prepared samples, standards and controls in the appropriate wells on the reagent strip. The sample is placed in the sample well as indicated shown in the package insert. The assay package insert specifies the volume of sample required to ensure proper performance of the assay.
Step 4	To load a SPR[®], • Open the SPR block door. • Place the SPR in the SPR block position directly above the corresponding reagent strip. CAUTION! <i>When placing the SPR in the SPR block position, do not apply pressure to the block position as this may cause the SPR to be ejected.</i> IMPORTANT! <i>Check the position of SPRs and reagent strips. The SPR color-coded dot must match the dot on the corresponding reagent strip.</i> CAUTION! <i>It is very important that all the correct SPRs are properly placed in the SPR block and the dot on top has a hole. The VIDAS cannot detect the type of SPR used nor the absence or presence of SPRs.</i>
Step 5	To load a reagent strip, • Lift the cover of the reagent strip section. • Holding it by its handle, insert a reagent strip into its assigned test position. • Slide the strip into the position until it seats fully in the channel. The strip should now be firmly fixed in the channel. CAUTION! <i>Strips and SPRs should not be loaded in advance but just before the corresponding test is performed, since preincubation in the sections may affect results. However, certain tests do require preincubation, in which case the strips can be incubated in the VIDAS (refer to the corresponding reagent package insert).</i> IMPORTANT! <i>It is very important to respect the required volume indicated in the assay package insert.</i> <i>It is important not to have solids in the sample that could clog the tip of the SPR.</i> <i>Do not use the strips if the aluminium foil is damaged or if reagents are leaking, as this could affect the accuracy of test results.</i> <i>Always make sure you put the correct patient sample into the assigned strip.</i> <i>For optimum operation of the instrument, the SPR[®] block and tray doors must be kept closed.</i>

- Step 6
- Close the SPR[®] block door(s).
- Step 7
- Lower the cover(s) of the reagent strip section(s).
- Step 8
- Run the assays.
- Step 9
- Section status switches from  to  and then . After having checked the reagent, **VIDAS** indicates the time of completion.
- Step 10
- When the assays are completed:
- A report is automatically printed (depending on the software configuration).
 - Section status switches from  (time of completion of the assay) to .
 - The section door indicator light flashes to indicate that the reagent strips and SPRs should be removed.
- Step 11
- Remove the completed reagent strips from each section used.
 - Remove the used SPRs, making sure that each carries a color-coded dot.

CAUTION!

If a SPR does not have its color-coded dot:

- ***Reject the result corresponding to the defective SPR.***
- ***Check that the dot has not become stuck on the SPR block or the SPR seal and if it has, then remove it.***
- ***Repeat the assay corresponding to the defective SPR.***
- ***Inform bioMérieux[®] Technical Assistance.***

When a SPR block door is closed after SPRs are removed,

- section status switches from  to .
- the section indicator light stops flashing, indicating that the section is free to perform a new assay.

6 Maintenance

Introduction

This chapter deals with:

- the routine maintenance operations which should be performed by the user.
- the preventive maintenance operations performed by bioMérieux® technicians or a qualified person trained by bioMérieux.

Preventive maintenance

Optimum performance of the **VIDAS** (within the limits of manufacturer specifications) depends on the preventive maintenance being performed by bioMérieux® technicians or a qualified person trained by bioMérieux **only**, as part of a maintenance contract.

The list of maintenance operations and their frequency is available from bioMérieux.

IMPORTANT! ***As well as the user maintenance operations described in this manual, periodic preventive maintenance must be performed by bioMérieux.***

User maintenance



DANGER !

Opening covers or removing components other than those maneuverable by hand may give access to parts of the equipment that can be dangerous to touch; exposed terminals may also be dangerous to touch.

Prior to any adjustment, replacement, servicing or repair, disconnect the instrument if it has to be opened.

6

WARNING! *After opening, if it is imperative to switch the instrument on, any adjustment, servicing or repair should be performed by a qualified, properly trained technician, well aware of the possible risks and appropriate service procedures.*

Tools required

No specific tools are required for preventive maintenance of **VIDAS**.

The basic equipment and products required are:

- sponges (Part no. 99 087),
- a flat screw-driver (**VIDAS**),
- a screwdriver for recessed head screws (only concerns **VIDAS blue**),
- disposable powderless gloves (latex-type),
- Dacron[®] swabs (Part no. 30 531),
- demineralized water,
- bleach solutions containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water,
- curved forceps,
- normal laboratory detergent solutions (7X[®], Alconox[®], Liquinox[®] or equivalent) used according to the manufacturers recommendations.

Summary of maintenance operations

Frequency Equipment	Weekly (S)	Monthly (M)	As required (B)
VIDAS blue analytical module	Clean SPR[®] block	- Decontaminate: – strip tray – strip preparation tray, – spill tray. - Test the pipette mechanisms using the bioMérieux[®] SA control reagent.	- Decontaminate: – strip tray, – strip preparation tray, – spill tray. (in the event of accidental contamination).
VIDAS analytical module	Clean SPR block .	- Decontaminate: – strip tray, – spill tray. - Test the pipette mechanisms using the bioMérieux SA control reagent.	- Decontaminate: – strip tray, – spill tray. (in the event of accidental contamination).
Computer			Clean : screen ⁽¹⁾.
Printer		Clean ⁽¹⁾.	Replace ink cartridge.
Bar code reader			Clean the window.

⁽¹⁾ For cleaning of the computer and printer, refer to Computer on page 6-20 and Printer on page 6-22.

Note: To check the pipette mechanisms, follow the instructions in the reagent package insert. To analyze the results, you must refer to the **printed report** and the package insert.

WARNING! *All the panels of the instrument should be regularly cleaned with a mild detergent diluted in water.*

Do not use hot water (maximum temperature: 60°C) to clean the instrument bodywork and removable parts (e.g. plastic trays, strip preparation tray).



Decontamination of the *VIDAS blue*

Decontamination involves:

- Routine decontamination which should be performed on a periodic basis.
- Cleaning of accidental spills (accidental contamination), which should be dealt with immediately.



DANGER !

Turn the VIDAS power switch to "OFF" and then disconnect the power cord.

Use POWDERLESS disposable gloves.

This operation must be performed once all assays are completed.

Do not allow disinfectant solution to spill into the instrument.



Maintenance

Decontamination of the VIDAS blue

Cleaning the SPR[®] block

(weekly)



DANGER !

This operation must be performed once all assays are completed. Use POWDERLESS disposable gloves.

Do not allow disinfectant solution to spill into the instrument.

To clean the SPR block the section needs to be fully open.
To do this:

- Open the section door slightly.
- Pull the safety latch towards you and then fully open the section door.

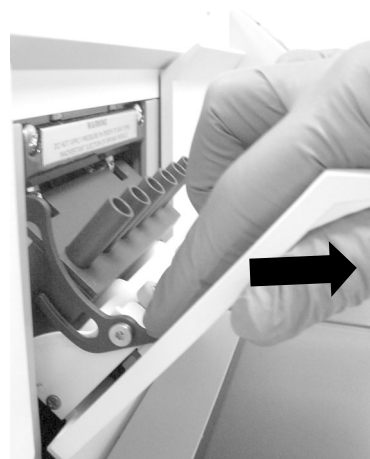
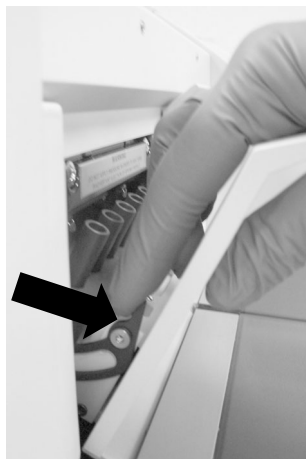


Fig. 6-1: Opening the section fully

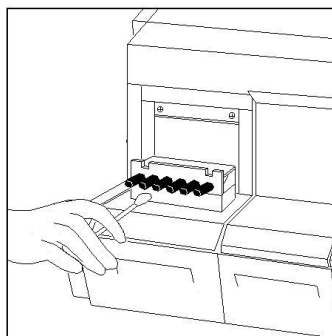


Fig. 6-2: Cleaning the SPR® block

- Using a **Dacron® swab** moistened with a detergent solution, carefully clean the interior of each SPR® sleeve (see Fig. 6-2).
- Repeat the previous operation using a new **Dacron swab** moistened with a bleach solution containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water.
- Allow the bleach solution to react for 10 minutes.
- Rinse each SPR sleeve using a new **Dacron swab** moistened with demineralized water.

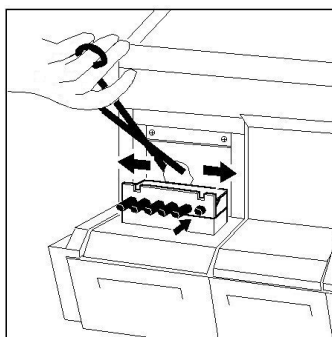


Fig. 6-3: Cleaning the rear of the SPR® block

- Using curved forceps, moisten a **sponge** with detergent and swab the rear of the SPR block, pushing each SPR sleeve individually back towards the interior of the section (see figure opposite).
- Repeat the previous operation using a new **sponge** moistened with a bleach solution containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water.
- Allow the bleach solution to react for 10 minutes.
- Moisten a **sponge** with demineralized water. Holding the sponge with curved forceps rinse the SPR® sleeves.



Maintenance

Decontamination of the VIDAS blue

- Close the SPR block door.

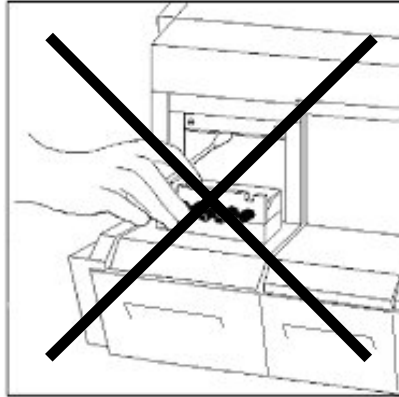


Fig. 6-4: Do not clean the seals situated above the SPR block

CAUTION!

Do not clean the seals situated above the SPR block (see Fig. 6-4) as they do not require cleaning other than when preventive maintenance is performed by the bioMérieux® Field Service Technician. In the event of accidental spills or contamination, it is imperative that you call bioMérieux Technical Assistance. Any handling of the seals may affect the performance of your instrument.

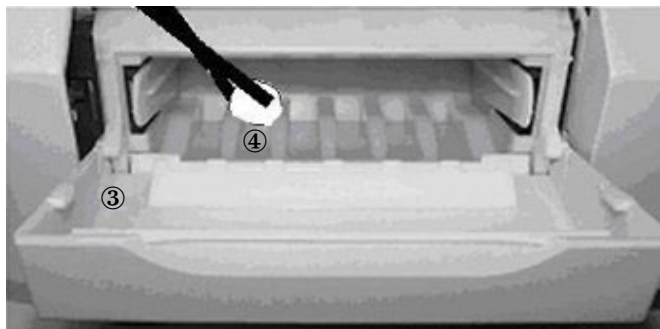
Cleaning the strip preparation tray

(monthly)

- Lift the handle on the strip preparation tray and tilt the tray forwards. The strip preparation tray will open.



Fig. 6-5: Opening the strip preparation tray



6

Fig. 6-6: Cleaning the strip preparation tray

- Using curved forceps and a **sponge** moistened with a detergent, carefully clean the front of the strip preparation tray ③ (Fig. 6-6) and the 6 channels ④ by sliding the **sponge** along each one.
- Repeat the previous operation using a new **sponge** moistened with a bleach solution containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water.
- Allow the bleach solution to react for 10 minutes.
- Carefully rinse using curved forceps and a new **sponge** moistened with demineralized water.



Maintenance

Decontamination of the VIDAS blue

Cleaning the reagent strip trays

(monthly)

- Raise the strip preparation tray until it is in its upright position.
- Use a suitable screwdriver to remove the 2 screws ① located under the strip preparation tray.
- Open the strip preparation tray by tilting it forwards.



Fig. 6-7: Dismantling the strip preparation tray

- With one hand (finger and thumb), grasp the 2 tabs inside the strip preparation tray, squeeze gently and pull forwards to remove the tray (see Fig. 6-8).



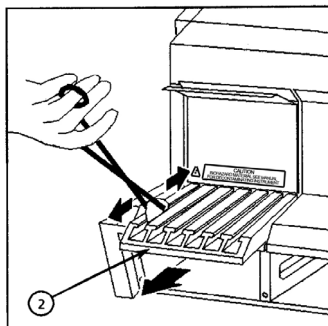
Fig. 6-8: Removing the strip preparation tray

This gives access to the reagent strip tray.

- Repeat this operation for each compartment.



- Manually pull the reagent strip trays ② to their outermost position (see Fig. 6-9).



6

Fig. 6-9: Repositioning the strip sections trays

- Moisten a **sponge** in the detergent solution. Holding the sponge with curved forceps, carefully clean the 6 channels of the reagent strip tray by sliding the **sponge** along each channel.
- Repeat the previous operation using a new **sponge** moistened with a bleach solution containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water.
- Allow the bleach solution to react for 10 minutes.
- Moisten a new **sponge** with demineralized water. Holding the sponge with curved forceps, rinse each tray.
- Push the reagent strip trays ② back in until they engage the tray drive mechanism (see Fig. 6-9).
You will feel a slight resistance during engagement.



Cleaning the spill tray (monthly)

- Remove the plastic tray ③ that sits underneath each reagent strip tray by sliding it towards you (see Fig. 6-10).

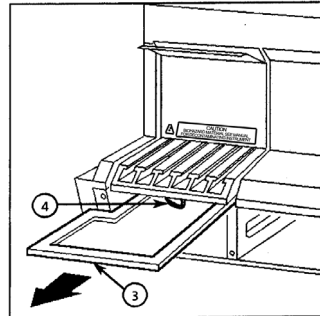


Fig. 6-10: Cleaning the spill tray

- Clean each tray with a **sponge** moistened with a detergent solution.
- Repeat the previous operation using a new **sponge** moistened with a bleach solution containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water.
- Allow the bleach solution to react for 10 minutes.
- Moisten a new **sponge** with demineralized water. Holding the sponge with curved forceps, rinse each tray.
- Carefully replace each tray ③. The edges of the tray must fit into the plastic grooves on each side.

WARNING! *The spill tray ③ must slide **BELOW** the electric wire ④ that is underneath the reagent strip tray.*



Reassembling the strip preparation tray and switching the analytical module back on

CAUTION! *Wait until all the parts are dry before reassembling them.*

Reassembling the strip preparation tray:

- Slide the strip preparation tray into its housing.

A "click" indicates that the strip preparation tray has been properly reassembled.

- Raise the strip preparation tray and screw the 2 screws back into place.
- Slide it back down into position.

CAUTION! *The VIDAS blue should not be used when the strip preparation tray is not in place.*

Powering on the analytical module:

- Reconnect the module to the power supply.
- Turn the power switch to the "ON" position.
- **Leave the module to pre-heat for 45 minutes.**
- Turn the power switch to the "OFF" position.
- Wait for approximately 1 minute and turn the power switch to the "ON" position.
- Wait for the module to reset (approximately 10 minutes) before attempting to use it again.

WARNING! *Dispose of sponges and swabs according to acceptable procedures for biohazardous material.*

Using the reagent for testing the pipette mechanisms: Quality Control VIDAS (QCV) – Reference 30706

This control reagent is a simple and rapid technique for testing the pipette mechanisms of your **VIDAS** instrument. You must perform the QCV test on all the **VIDAS** instrument positions at least once a month or anytime that a pipetting problem is suspected.

For further information on this test, refer to the package insert included in the kit.

Read the package insert carefully before performing the test.

Decontamination of the VIDAS

Decontamination involves:

- Routine decontamination which should be performed on a periodic basis.
- Cleaning of accidental spills (accidental contamination), which should be dealt with immediately.



DANGER !

Turn the VIDAS power switch to "OFF" and then disconnect the power cord.

Use POWDERLESS disposable gloves.

This operation must be performed once all assays are completed.

Do not allow disinfectant solution to spill into the instrument.

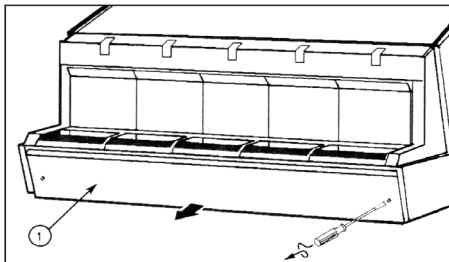


Fig. 6-11: Removing the front panel

- Remove the screws from the front panel ① of the module below the reagent strip trays and pull the panel off (see Fig. 6-11).

Cleaning the SPR[®] block (weekly)



DANGER !

*This operation must be performed once all assays are completed. Use **POWDERLESS** disposable gloves.*

Do not allow disinfectant solution to spill into the instrument.

6

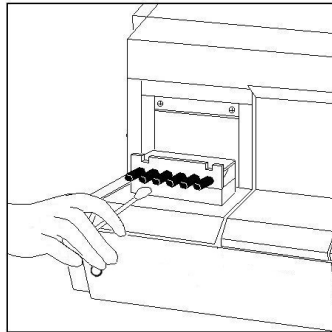


Fig. 6-12: Cleaning the SPR[®] block

- Open the door of the section containing the SPR block.
- Using a **Dacron[®] swab** moistened with a detergent solution, carefully clean the interior of each SPR sleeve (see Fig. 6-12).
- Repeat the previous operation using a new **Dacron swab** moistened with a bleach solution containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water.
- Allow the bleach solution to react for 10 minutes.
- Rinse each SPR sleeve using a new **Dacron swab** moistened with demineralized water.

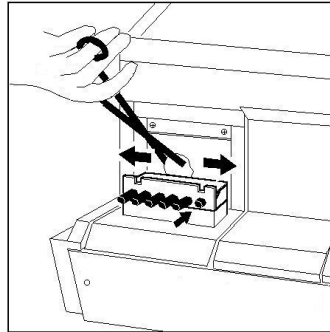


Fig. 6-13: Cleaning the rear of the SPR® block

- Using curved forceps, moisten a **sponge** with detergent and swab the rear of the SPR block, pushing each SPR sleeve individually back towards the interior of the section (see Fig. 6-13).
- Repeat the previous operation using a new **sponge** moistened with a bleach solution containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water.
- Allow the bleach solution to react for 10 minutes.
- Moisten a **sponge** with demineralized water. Holding the sponge with curved forceps rinse the SPR sleeves.
- Close the SPR block door.

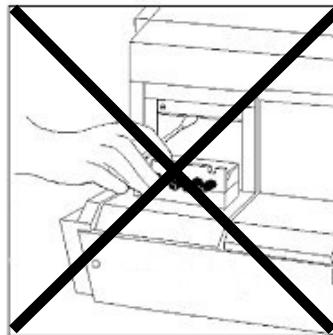


Fig. 6-14: Do not clean the seals situated above the SPR block

CAUTION!

Do not clean the seals situated above the SPR® block (see Fig. 6-14) as they do not require cleaning other than when preventive maintenance is performed by the bioMérieux® Field Service Technician. In the event of accidental spills or contamination, it is imperative that you call bioMérieux Technical Assistance. Any handling of the seals may affect the performance of your instrument.

Cleaning the reagent strip trays (monthly)

- Manually pull the reagent strip trays ② to their outermost position (see Fig. 6-15).

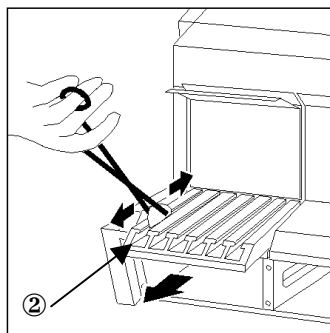


Fig. 6-15: Repositioning the strip sections trays

- Moisten a **sponge** in the detergent solution. Holding the sponge with curved forceps, carefully clean the 6 channels of the reagent strip tray by sliding the **sponge** along each channel.
- Repeat the previous operation using a new **sponge** moistened with a bleach solution containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water.
- Allow the bleach solution to react for 10 minutes.
- Moisten a new **sponge** with demineralized water. Holding the sponge with curved forceps, rinse each tray.
- Push the reagent strip trays ② back in until they engage the tray drive mechanism (see Fig. 6-15).
You will feel a slight resistance during engagement.

Cleaning the spill tray
(monthly)

- Remove the plastic tray ③ that sits underneath each reagent strip tray by sliding it towards you (see Fig. 6-16).

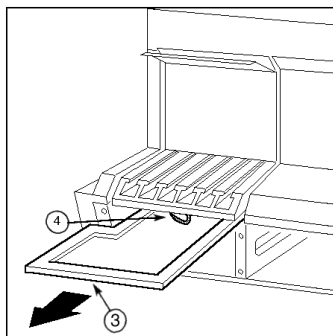


Fig. 6-16: Cleaning the spill tray

- Clean each tray with a **sponge** moistened with a detergent solution.
- Repeat the previous operation using a new **sponge** moistened with a bleach solution containing 0.5-0.6% active chlorine (5.5 to 6.6 g/l sodium hypochlorite); these solutions should be prepared in demineralized water.
- Allow the bleach solution to react for 10 minutes.
- Moisten a new **sponge** with demineralized water. Holding the sponge with curved forceps, rinse each tray.
- Carefully replace each tray ③. The edges of the tray must fit into the plastic grooves on each side.

WARNING! *The spill tray ③ must slide BELOW the electric wire ④ that is underneath the reagent strip tray.*

Replacing the front panel and switching the analytical module back on

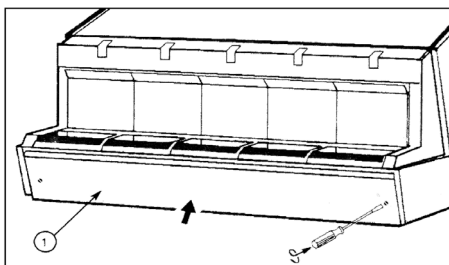


Fig. 6-17: Replacing the front panel

- Replace the front panel ① (see Fig. 6-17).
- Reconnect the module to the power supply.
- Turn the power switch to the "ON" position.
- **Leave the module to pre-heat for 45 minutes.**
- Turn the power switch to the "OFF" position.
- Wait for approximately 1 minute and turn the power switch to the "ON" position.
- Wait for the module to reset (approximately 10 minutes) before attempting to use it again.

WARNING! *Dispose of sponges and swabs according to acceptable procedures for biohazardous material.*

Using the reagent for testing the pipette mechanisms: Quality Control VIDAS (QCV) – Reference 30706

This control reagent is a simple and rapid technique for testing the pipette mechanisms of your **VIDAS** instrument. You must perform the QCV test on all the **VIDAS** instrument positions at least once a month or anytime that a pipetting problem is suspected.

For further information on this test, refer to the package insert included in the kit.

Read the package insert carefully before performing the test.

Computer

Cleaning the screen

(as required)

From any window (no assays should be in progress):

- Quit all programs by clicking on the  icon in the top right-hand corner of the windows.

To shut down the computer,

- Click on the  button in the bottom left-hand corner of the screen or press one of the "Windows" keys either side of the space bar,
- Select "Shut down".

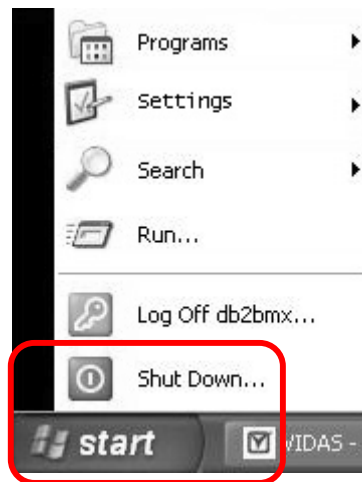


Fig. 6-18: Shutting down Windows®

The following window appears:



6

Fig. 6-19: Shutting down the computer

- Select "Shut down".
- Click "OK".

The computer will stop and shut down.

- Switch off the computer (if necessary) and the screen.
- Clean the screen with a dry anti-static cloth or use a special screen cleaner.
- Turn on the screen and the computer.

Refer to the section entitled "Starting **VIDAS PC**" in Chapter 3 of the **VIDAS PC** User's Manual.

~~The **VIDAS** retests some of its mechanical and optical systems.~~

Printer

Cleaning

(monthly)

- Refer to the Printer User's Manual.

WARNING! *Never use alcohol or solvents to clean the printer as these chemicals could damage components or the housing.*

Do not allow water to spill into the printing mechanism or onto electronic components.

Do not use hard-bristle brushes or abrasive materials.

Do not spray lubricants into the printer.

Replacing the ink cartridge

(as required)

As soon as the print quality begins to deteriorate,

- Change the ink cartridge.

To do so:

- Refer to the Printer User's Manual.

Bar code reader

Cleaning

(as required)

- Clean the reader window using a soft cloth.

7 Troubleshooting

Introduction

This chapter describes the problems that may occur with the bar code reader.

In case of a problem, see Chapter 12 "Troubleshooting" in the **VIDAS PC** User's Manual.

The reader does not emit a beam of light

- Check that the computer is switched on.
- Check that the cables are securely connected (see the procedure for connection, page 4-8).
- Check that the trigger is working.

After verification, if the reader does not function properly:

- Repeat the installation procedure in section "Starting the VIDAS".

If the problem persists, call bioMérieux® Technical Assistance or your local bioMérieux representative.

Reader fails to read bar codes

There are several possibilities:

- The bar codes are unreadable:

IMPORTANT! ***To be readable, bar codes must be complete, unstained and untorn.***

If the configuration sheet provided with the reader is missing or unreadable, call bioMérieux Technical Assistance or your local bioMérieux representative.

- The reader window is not clean:
 - Check that the reader window is clean and if necessary clean it using a soft cloth.
 - Repeat the reading.
- The reading distance is incorrect:
 - Slowly move the reader away from and/or towards the bar code until the optimal position for reading has been reached.

Note: *A beep indicates that reading has been performed.*

- A keyboard error has occurred:
 - Check that the upper case key (<Maj> or <Caps lock>) is disabled.
 - Repeat the reading.

If these failures recur, call bioMérieux Technical Assistance or your local bioMérieux representative.

Error 161

If the **VIDAS PC** software displays "Error 161" following a reading:

- Refer to Chapter 12 in the **VIDAS PC** User's Manual.

8 Glossary

ASSAY ANALYSIS

Interpretation of data using sample assay data, standard assay data, and thresholds for data comparison.

These calculations can be different for each type of assay and enable interpretation of the assay result.

ASSAY CODE

A two-, three- or four-character designation for an assay used in the **VIDAS**. Assays are entered into the system, for example, to create a Work List, using the assay code.

ASSAY COMPATIBILITY

A property in which two or more assays use the same .

ASSAY KIT

A package containing a set of Reagent Strips, SPR[®]s, and a package insert along with any necessary controls, standards, sample treatment agents and the MLE card.

BAR CODE

A series of lines printed on the label of a Reagent Strip and on the MLE card. The encoded information can be read and interpreted by the scanner and used to identify the strip.

BCI

Bidirectional Computer Interface (bidirectional connection between 2 computers).

CALIBRATION

The process of adjusting the standard curve of a quantitative assay lot or storing of the calibrator's RFV for a qualitative assay.

CENTRAL PROCESSING UNIT

The portion of a computer that is responsible for processing software instructions.

CONFIGURATION

A group of elements consisting of an instrument, its operating software and the peripheral(s) which can be connected to it. .

CONNECTION

Link between the computer and the peripherals or with the central laboratory information system via input and output ports.

Glossary

DUAL REAGENT STRIP	A strip consisting of a jointly attached sample reference Reagent Strip (left) and a sample test Reagent Strip (right).
FLUORESCENCE	A physical process in which a substance emits light at a certain wavelength after exposure to light at another wavelength. This is the measurement process used in the VIDAS .
OPTICAL CUVETTE	The last well on the Reagent Strip. It is made of optically clear plastic that permits the scanner to take an accurate fluorometric reading of the substrate.
OPTICAL SCANNER	A component of the analytical module which reads bar codes and measures the intensity of fluorescence of an assay.
POSITION	A section consists of 6 positions numbered from 1 to 6 from left to right. Each position corresponds to a SPR [®] slot in the SPR block.
PREDEFINED SECTION	Compatible tests (max. 6) grouped under the same number.
PROTOCOL	A specific sequence of computer-controlled activities (pipetting, mixing, incubating, reading, etc.) needed to perform an assay.
REAGENT	A package consisting of a single or a dual strip and a SPR.
REAGENT STRIP	A polypropylene strip of 10 wells with a foil seal and paper label. The first well is the sample well and the other eight wells contain the various reagents required for the immunoassay. The last well of the strip is the optical cuvette containing the substrate.
REAGENT STRIP TRAY	A temperature-controlled tray with a plastic cover that can hold six reagent strips or three dual reagent strips. Also called Section tray.
RESERVED	A reserved predefined section is one in which the system assigns the Reagent Strips and SPRs to specific positions in the analytical module.
RESULT	The interpretation of the test value in a defined unit.

RFV	Relative Fluorescence Value. The difference between the final and the initial (background) fluorescent readings of a reagent strip.
SAMPLE	The patient material being tested.
SECTION	A microprocessor-controlled assay processing unit in the VIDAS instrument. Each module has five sections, labeled A through E. Each incubator contains a SPR [®] block with channels for six Reagent Strips or three Dual Reagent Strips. A SPR position and its corresponding Reagent Strip channel make up one test position.
SEQUENCE NUMBER	A number printed on the Reagent Strip and encoded into the bar code. It can be read by the optical scanner and printed on the assay report. It uniquely identifies a particular reagent strip.
SPR[®]	A specially designed plastic pipette-shaped device with its inside wall coated with antibody, antigen, or other treatments that allow capture of a target analyte. Each SPR has a corresponding Reagent Strip.
SPR[®] BLOCK	A temperature-controlled block with receptacles to hold six SPRs. Each has a position for a corresponding Reagent Strip immediately below it in the section. A tilt-down door provides access to the SPR [®] .
STANDARD	A solution containing a known analyte concentration. The RFV obtained from testing a standard is used to calculate concentrations and to interpret patient samples or controls.
STRIP PREPARATION TRAY	A tray with 6 positions located under each reagent strip tray. It is used to prepare tests for a specific section as it can hold either 6 individual strips or the boat included in the reagent kit.
SUBSTRATE	A substance in the Reagent Strip that is broken down enzymatically to create a compound that fluoresces.
TARGET ANALYTE	A biological element to be assayed (antigens, antibodies, ...)
TEST	Term which refers to the combination of sample identifier (sample ID or patient ID) and assay code with which the analysis is to be performed.

Glossary

TEST VALUE

For qualitative tests. The result calculated by **VIDAS** using the RFV (Relative Fluorescence Value) of the sample and which enables the interpretation of results.

VIDAS MODULE

The **VIDAS** analyzer / reader.

9 Index

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Notes

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Notes

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